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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,476	12/18/2001	Jonah Shacknai	00-40175-US-P	4300

7590

09/15/2005

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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/022,476	<b>Applicant(s)</b> SHACKNAI ET AL. 3	
	<b>Examiner</b> NEIL LEVY	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 12-117 is/are pending in the application.  
 4a) Of the above claim(s) 4,9,13,15,20,21,24-27,30-115 stand is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1,3,5-8,12,14,16-20,22,23,28,29,116 and 117 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☒ Claim(s) 1,3,-9,12-117 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 9, 13, 15, 20, 21, 24-27, 30 - 1 15 stand withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Election was made without traverse in the reply filed on 8/3/04.

Claims 1,3, 12, 14, 17-19, 22, 23, 28, 29, 1 16 and 1 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al - 6429,231 in view of remarks of 1 1/23/04, Bonnar et al '93 and further in view of Robinson '39 or Merck '72.

The rejection of record is maintained.

Bhagwat applies preparations consisting essentially of sulfur and sulfacetamide, as active ingredients (example 2, 5% S, 10% sulfacetamide, the only instant actives, as a Lotion, applied to human skin, to treat dermatological disorders (col. 1 , Summary). Since mites are always present (applicant and Bonnar) on human skin, any disorder, manifested as indicated, would be treatable by Bhagwat's

methods; Application of sulfur and sulfacetamide in a dermatologically acceptable carrier to skin.

Robinson provides one example of mite infestation with any of the skin disorders recited by the prior art record , associated with the dermatological syndromes disclosed and treated by Bhagwat. Repeated washings are necessary.

It would have been obvious to a person of ordinary skill in the dermatological art at the time the invention was made desiring to control and remediate visible lesions, irritation, inflammation, or the like dermatological disorders and cutaneous infections, to utilize the methods of Bhagwat - application of sulfur and sodium sulfacetamide in dermatologically acceptable carriers.

. There is no patentable distinction evident to examiner of the instant method steps from Bhagwat steps, .

Claims 1,3, 5-8, 12, 16, 1 16, 1 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson or White 1894, in view of Allen - 4895727 and declaration of Patel.

Robinson, (above) and white (p. 228, 230 external) show sulphur and

sulphurated line, is applied as instantly claimed, to kill mites. Robinson teaches sulphur

and suitable carriers, and washing of the skin, to treat mites, but neither teach the combination with sulfacetamide. However, Allen teaches the desirability of (summary) enhancing active agents, inclusive of antiparasitic agents (col. 3, lines 39-42) and antimicrobial agents, for mites (8., col. 5). Sulfurated line (claim 3) is also specifically mentioned as an agent enhanced by zinc sulfate, as are other sulfides, sulfates, sulfoxides, sulfuric acids, sulfonamides, sulfones thiosulfates and sodium sulfacetamide.

Claims 1,3, 18, 1 16 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Robinson '39 explained by White, 1894. The rejection of record is maintained.

Robinson teaches the instant method of treating scabies by application of sulphur ointment (p. 638, col. 2).

The ointment is made from precipitated or sublimed sulphur, & has some sulphurous and sulphuric acids as impurities of sublimed sulphur, and lime sulphate (p.227). Thus, the sulphur of Robinson, applied as pharmacologically dictated includes sulfur derivatives of the instant claims.

There is no other active required by Robinson.

Applicant's arguments filed on 6/22/05 have been fully considered but they are not persuasive. Applicant's arguments are understood as infestations constitute a quantitatively different mite presence than normal and are of clinical health significance. Examiner finds that the prior art teaches the same instant steps of application to the skin of the instant actives; whether or not mites are present, or how many, is not of patentable distinction.

### ***Conclusion***


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NEIL S. LEVY  
PRIMARY EXAMINER